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11 UNITED STATES DISTRICT COURT
12 SOUTHERN DISTRICT OF CALIFORNIA

14 GEN-PROBE INCORPORATED,

15 Plaintiff,

16 v.

17 VYSIS, INC.,

18 Defendant.

No. 99 CV 2668H AJB

MEMORANDUM OF POINTS AND AUTHORITIES
OF GEN-PROBE INCORPORATED IN RESPONSE
TO VYSIS' MOTION: (1) FOR A STAY OF
PROCEEDINGS AND, ALTERNATIVELY, (2) TO
DISMISS COUNT FOUR UNDER FEDERAL RULE
OF CIVIL PROCEDURE 12(b)(6)

Date: April 24, 2000
Time: 10:30 a.m.
Dept.: Courtroom 1

Trial Date: Not Yet Set

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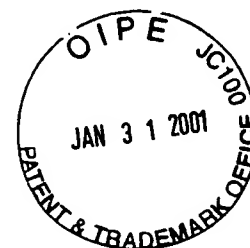
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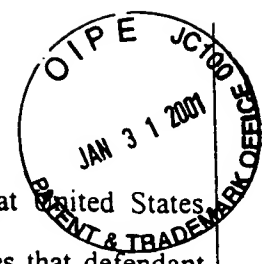
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I. INTRODUCTION.

In this action, plaintiff Gen-Probe Incorporated seeks a declaration that Patent Number 5,750,338 (the "'338 patent") is invalid. Gen-Probe also alleges that defendant Vysis, Inc. has committed unfair competition by enforcing the '338 patent against Gen-Probe in bad faith, while knowing the patent to be invalid.

In response to Gen-Probe's complaint, Vysis has declared to the United States Patent and Trademark Office (the "Patent Office") that the '338 patent is "partly inoperative" due to an "error" in the prosecution of the patent. (See Page 127 of Exhibit E to Declaration of John L'Estrange In Support of Vysis' Motion ("Vysis Exh. ____").) Rather than submit the existing patent to scrutiny in this Court, Vysis seeks to change the claims of the patent through a "reissue" proceeding in the Patent Office. By federal regulation, the reissue proceeding will be conducted *ex parte*, and Gen-Probe will be precluded from participating in that proceeding in any meaningful fashion.

Gen-Probe will be prejudiced by any delay in the adjudication of its claims until after the reissue proceeding is completed. If the Court elects to delay further proceedings in this case while Vysis seeks to change the patent in the Patent Office, the Court should impose conditions that are adequate to protect Gen-Probe against the prejudice that it will suffer as a result of the delay. Such conditions are essential, and the Court should impose a stay *only* in conjunction with the imposition of conditions required by equity and fairness. Furthermore, any stay of this case should be complete – it should not be a partial, one-sided stay that permits Vysis alone to keep this action alive for the sole purpose of obtaining unilateral discovery.

Finally, the Court should deny Vysis' alternative motion to dismiss Gen-Probe's fourth claim of relief for unfair competition. According to Vysis, the mere existence of a license agreement for the '338 patent insulates Vysis from any claim of unlawful, unfair or fraudulent business practices under California law. Vysis' argument ignores the fact of Vysis' bad faith enforcement of the patent, through the license agreement and other conduct. Vysis' argument also ignores decisions by the United States Court of Appeals for the Federal Circuit that confirm the vitality of unfair competition claims in the circumstances alleged in the First Amended Complaint.

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1 **II. FACTUAL BACKGROUND.**

2 In light of the procedural posture of this case, the Court must accept as true the facts that
3 Gen-Probe asserts in its operative complaint. *E.g., Cooper v. Pickett*, 137 F.3d 616, 623 (9th Cir.
4 1998); *NL Industries, Inc. v. Kaplan*, 792 F.2d 896, 898 (9th Cir. 1986).

5 **A. The Parties**

6 **1. Gen-Probe Incorporated.**

7 Gen-Probe was founded in San Diego in 1984 as a small "start up" company
8 seeking to develop products based on the discoveries of a local research scientist. Over time,
9 Gen-Probe has become one of the largest biotechnology firms in San Diego. Gen-Probe now
10 maintains its principal offices and research facilities at 10210 Genetic Center Drive in San Diego,
11 where it employs over 600 scientists and staff.

12 Gen-Probe has developed and continues to develop diagnostic tests that seek to detect the
13 DNA or RNA of infectious organisms. These types of tests are generally referred to as "genetic
14 probes" or nucleic acid tests ("NAT"). Gen-Probe now markets genetic probe products that test
15 for a wide range of microorganisms that cause tuberculosis, strep throat, pneumonia, sexually
16 transmitted diseases, and fungal infections.

17 **2. Vysis, Inc.**

18 Defendant Vysis, Inc. is a public corporation that maintains its principal
19 place of business in Downers Grove, Illinois. It is a subsidiary of BP Amoco plc. Vysis claims
20 that it is the assignee of the '338 patent. While Vysis markets numerous products, it has never
21 been profitable.

22 **B. Gen-Probe's NAT Test Kits.**

23 In 1996, Gen-Probe received a grant of \$7.7 million from the National Institutes of
24 Health to develop NAT tests to detect HIV and hepatitis C in blood donated for transfusion. At the
25 time of the grant, existing screening tests relied upon the detection of antibodies to the viruses
26 when those antibodies were produced by the immune system. Significantly, a "window" period
27 exists between the time a person is first infected with a virus, such as HIV or hepatitis C, and the
28 time that the body first produces antibodies to the disease. The NIH-funded research was intended

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1 to expedite development of NAT tests that could rapidly and directly detect the HIV and HCV
2 viruses themselves, even before the body first produced antibodies to the viruses. These tests
3 would thus reduce the "window" period in which infected blood might be unknowingly transfused.

4 Gen-Probe succeeded in developing the NAT tests sought by the NIH. Gen-Probe's tests
5 have been in use by the American Red Cross and America's Blood Centers since March 1999,
6 pursuant to an Investigational New Drug ("IND") application.¹ ("A Purity Quest; Local Biotech's
7 Ultra-Sensitive Blood Screening Could Cut Risk of AIDS, Hepatitis," *San Diego Union*, March
8 25, 1999, page C-1). In blood tested by the American Red Cross, Gen-Probe's products have
9 detected hepatitis C and HIV in donated blood after the viruses escaped detection by the prior
10 antibody-based methods. ("New Blood Screening Finds Virus Others Missed; Experimental Test
11 Turns Up Hepatitis C in Donated Blood," *San Diego Union*, April 2, 1999, page B-2.)

12 Further clinical trials in the United States of the HIV/HCV blood screening tests will
13 commence this month. Commercial sales in the United States of kits containing its HIV/HCV
14 blood-screening test will likely begin during 2000. Gen-Probe has already received regulatory
15 approval of the tests in France and Australia.

16 **C. The '338 patent and the prosecution history.**

17 This litigation concerns the validity of the '338 patent and whether Gen-Probe's
18 products and activities infringe that patent. The specification of the '338 patent purports to teach a
19 method that combines isolation of a target DNA in a step known as "target capture", and a
20 subsequent process in which many copies of that DNA are made (the "amplification" step).

21 The '338 patent prosecution history began on October 23, 1986 with the filing of United
22 States Patent Application Number 922,155 ("the '155 Application"). This application claimed a
23 method for target capture, but it did not disclose the combination of target capture and
24 amplification that the '338 patent claims. A continuation-in-part application of the '155
25 Application, United States Patent Application Number 136,920 was filed on December 21, 1987

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27
28 ¹ Because of the importance of the NAT tests, they are regarded by the FDA as a "drug" rather
than as an ordinary diagnostic product

1 and this application is the first the Collins' family of patents to disclose target capture couples with
2 target amplification.

3 The '338 patent prosecution history began on October 23, 1986 with the filing of United
4 States Patent Application Number 922,155. This application claimed a method for target capture,
5 but it did not disclose the combination of target capture and amplification that the '338 patent
6 claims.

7 The prosecution history of the patent is extraordinary. The original application eventually
8 led, through a series of at least six subsequent applications over a period of almost twelve years, to
9 the issuance of the '338 patent in May 1998. In the course of prosecution, Vysis several times
10 abandoned its applications, and was forced to petition the Patent Office to revive them.

11 **D. The History Of This Litigation.**

12 Almost immediately after issuance of the '338 patent, through a thinly-veiled threat
13 of an infringement suit, Vysis asserted the '338 patent against Gen-Probe's NAT kits. (First
14 Amended Complaint, ¶ 20, Exh. 1 To Notice of Lodgment ("NOL")) On June 22, 1999, in order
15 to avoid last-minute complications in the introduction of those kits, Gen-Probe signed a license to
16 the '338 patent. (Vysis Exh. D.) Pursuant to the terms of the license, Gen-Probe must pay
17 royalties to Vysis until such time as the patent is declared invalid. However, Gen-Probe has no
18 obligation to pay royalties unless its products are covered by the '338 patent. *Id.*

19 This suit commenced on December 22, 1999, when Gen-Probe filed a complaint in the
20 United States District Court for the Southern District of California. (Declaration of Patrick M.
21 Maloney ("Maloney Decl."), ¶ 2.) Gen-Probe sought a declaration that the '338 patent is invalid
22 and a declaration that Gen-Probe's products and activities, namely its NAT test kits, do not
23 infringe the '338 patent.

24 On January 6, 2000, Gen-Probe informally disclosed to Vysis several prior art references
25 that Gen-Probe believed render the '338 patent invalid because the technology claimed in the
26 patent was anticipated by or obvious in light of the work of others. (Vysis Exh. B.) Vysis
27 responded on January 19, 2000 that it believed that the references did not effect the validity of the
28 '338 patent. (Vysis Exh. C.)

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On January 26, 2000, before Vysis responded to the Complaint, Gen-Probe filed and served on Vysis a First Amended Complaint that included the prior invalidity and non-infringement counts and also added counts for a declaration that Gen-Probe is not obligated to make royalty payments to Vysis pursuant to the license concerning the '338 patent and for violations of the California Unfair Business Practices Act, California Business and Professions Code §17200 *et seq.* (the Unfair Competition Claim). (Maloney Decl., ¶ 3.) In the unfair competition claim, Gen-Probe asserts that Vysis has committed acts of unfair competition by persisting to enforce the '338 patent even though Vysis knows that the patent is invalid.

Notwithstanding Vysis' January 19 response to the contrary, on March 8, 2000, Vysis apparently filed a reissue application with the Patent and Trademark Office, declaring the '338 patent to be "partially inoperative." (Vysis Exh. F.) Contrary to the express requirements of the Patent Office (Manual of Patent Examination Procedures ("MPEP") § 1442.04), Vysis failed to disclose in its reissue application that the patent that it seeks to amend is the subject of pending litigation.

After the parties served one another with initial rounds of discovery, the parties agreed to stay the discovery, and Vysis responded to the First Amended Complaint on March 9, 2000 by filing the instant motion for a stay, which alternatively requests that Gen-Probe's unfair competition claim be dismissed. (Maloney Decl. ¶¶ 4-8.) The parties recently again stayed all discovery pending the resolution of the instant motion. (*Id.*, ¶ 9.)

III. IF THE COURT ELECTS TO IMPOSE A STAY, IT SHOULD IMPOSE CONDITIONS THAT WILL ENSURE THE PROMPT RESOLUTION OF THE PATENT OFFICE PROCEEDINGS AND PROTECT GEN-PROBE FROM THE PREJUDICIAL EFFECTS OF THE DELAY

In response to the complaint in this case, Vysis has elected to declare the '338 patent "partially inoperative" (Vysis Exh. E, p. 127) and now seeks to change the patent before submitting it to scrutiny by this Court. In considering Vysis' motion for a stay, the Court should evaluate and balance (1) the benefits that may flow from the reissue process, (2) the hardships and prejudice that staying the litigation while reissue is pending will cause the parties, and (3) how far the litigation has proceeded. *Xerox v. 3Com Corp.*, 69 F.Supp.2d 404, 406-407 (W.D.N.Y. 1999). Indeed, despite the perceived advantages of a stay pending a Patent Office determination, several

1 courts have denied a stay where the stay would cause undue prejudice or present a clear tactical
2 disadvantage to the non-moving party. *E.g., GPAC, Inc. v. D.W.M. Enterprises, Inc.*, 144 F.R.D.
3 60 (D.N.J. 1992); *Freeman v. Minnesota Mining & Mfg. Co.*, 661 F. Supp. 886, 888 (D. Del.
4 1987).

5 A. A stay will likely delay resolution of this case by over a year.

6 If a stay is granted pending the completion of the reissue proceeding, significant
7 delay in adjudicating Gen-Probe's claims will inevitably result. Gen-Probe will be prejudiced by
8 that delay.

9 To begin with, Vysis' suggestion that its reissue proceedings will be conducted in an
10 expeditious manner greatly overstates the speed with which the Patent Office disposes of reissue
11 proceedings in general and, given the conduct of Vysis thus far, the speed with which it is likely to
12 dispose of Vysis' application in particular. For example, on average, even though the Patent
13 Office deems reissue proceedings "special," it still requires in excess of one year to dispose of
14 such matters in the Patent Office. According to the 1998 Patent and Trademark Office Annual
15 Report - Fiscal Year 1998: A Patent And Trademark Office Review -- the average time in 1998 to
16 process a utility, plant, or reissue application was 16.9 months, and the Patent Office *hoped* to
17 reduce this to an *average* of 10 months by 2000. (NOL, Exh. 2, p. 18.) Moreover, the Manual of
18 Patent Examining Procedures, in section 1442.01, permits the Patent Office to grant the applicant
19 an extension of time within which to respond to any office action that is long and complex. Given
20 the '338 patent's lengthy and tortured prosecution history, it is not unreasonable to assume that the
21 reissue proceedings will take longer than average.²

22 The evidence already suggests that Vysis is not motivated to resolve the pending reissue
23 proceedings as quickly as its moving papers might suggest. Vysis has failed to comply with
24 Section 1442.04 of the MPEP. This section required Vysis to disclose to the Patent Office in its

25 ² One reason for that delay is that reissue applicants may file continuation applications. Thus,
26 although the time for any individual response may be limited, a reissue applicant such as Vysis
27 may delay the ultimate proceedings endlessly through continuation practice and filibuster. *Cf.*
28 *United Sweetener USA, Inc. v. Nutrasweet Co.*, 766 F. Supp. 212, 218-219 (D. Del. 1991) (court
concerned that litigants would use Patent Office appeals following reexamination to its tactical
advantage).

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1 initial reissue application the fact that the '338 patent is the subject of litigation. Among other
2 things, that disclosure would prompt expediting processes within the Patent Office (albeit subject
3 to the potential delay and filibuster of continuation practice).³

4 **B. Reissue will not dispose of this litigation.**

5 Implicit in Vysis' motion for a stay is the suggestion that its efforts to obtain reissue
6 of the '338 patent will dispose of this litigation. This suggestion is without any basis. As
7 discussed below, when the stay terminates, this case will return to the very same posture that it was
8 in when Vysis filed its reissue application.

9 Vysis contends that the reissue proceeding will somehow expedite the resolution of this
10 case upon the termination of the stay and the resumption of proceedings in this Court. In fact, the
11 only clear result of Vysis' belated reissue application will be delay in the adjudication of the issues
12 raised by the complaint in this case.

13 Contrary to Vysis' express suggestion, the fact that the patent will have undergone further
14 *ex parte* examination by the Patent Office in the course of the reissue process will *not* change the
15 scope of review in this Court when the reissue proceeding is complete. *T.J. Smith and Nephew*
16 *Ltd. v. Consolidated Medical Equipment, Inc.*, 821 F.2d 646, 648 (Fed. Cir. 1987) ("The
17 presumption of validity ... is not 'strengthened' by reissue"); *Fromson v. Advance Offset Plate,*
18 *Inc.*, 755 F.2d 1549 (Fed. Cir. 1985) (same); *Johnson & Johnson, Inc. v. Wallace A. Erickson &*
19 *Co.*, 627 F.2d 57 (7th Cir. 1982) (reissue proceedings "have no effect whatever on the judicial
20 process"); *PIC Inc. v. Prescon Corp.*, 495 F.Supp. 1302 (D. Del. 1980) (same; noting *ex parte*,
21 non-adversarial nature of Patent Office reissue proceedings).

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26 _____
27 ³ This requirement for disclosure of pending litigation is neither an idle nor insignificant
28 obligation. In at least one reported instance, a reissue applicant's failure to comply with this
litigation disclosure requirement contributed to a finding of inequitable conduct. *See Critikon, Inc.*
v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253 (Fed. Cir. 1997).

1 Thus, when the reissue proceeding is complete, the validity of the claims of the patent must
2 be determined in this Court without deference to the Patent Office:

3 The Courts are the final arbiter of patent validity and, although
4 courts may take cognizance of, and benefit from, the proceedings
5 before the patent examiner, the question is ultimately for the courts
6 to decide, without deference to the ruling of the patent examiner.

7 *Quad Environmental Tech v. Union Sanitary Dist.*, 946 F.2d 870, 876 (Fed. Cir. 1991).

8 Irrespective of whether Vysis retains the existing, "partially inoperative" claims of the '338
9 patent or obtains new claims, this Court will still need to evaluate Gen-Probe's claims of
10 non-infringement and invalidity. Additionally, the reissue proceedings cannot dispose of
11 Gen-Probe's claim for unfair competition arising out of Vysis bad-faith enforcement of the '338
12 patent, which it now admits is "partially inoperative." Nor can the reissue proceedings resolve the
13 claim that the patent is unenforceable because Vysis engaged in inequitable conduct while
14 prosecuting the '338 patent. *See* MPEP 1448; *e.g. Enprotech Corp. v. Autotech Corp.*, 15 U.S.P.Q.
15 2d 1319 (N.D. Ill. 1990). Nor can the Patent Office consider Gen-Probe's claim of unfair
16 competition. Simply put, reissue will not dispose of this litigation.

17 **C. Gen-Probe will suffer prejudice from the imposition of a stay.**

18 Delay in resolving the issues raised by the First Amended Complaint will prejudice
19 Gen-Probe and benefit Vysis. The Court need not search for a hidden motive behind Vysis pursuit
20 of reissue proceedings and its failure to expedite the reissue proceedings as set forth above. That
21 motive for delay arises from Gen-Probe's representations to the Court and Vysis that, in light of
22 Vysis express and implied threats, it currently intends to continue to pay royalties on the '338
23 patent during the pendency of this suit. Thus, delay in the ultimate resolution of the reissue and
24 this case works to Vysis' benefit. Indeed, if the reissue proceeding or this action results in a
25 finding that the entirety of the claims of the '338 patent are invalid, Vysis could receive the benefit
26 of millions of dollars of additional royalty payments simply as a result of the delay caused by the
27 reissue application.

28 The prejudice to Gen-Probe from delay is particularly disturbing given Vysis' precarious
financial status. According to Vysis' public reports, it has not yet generated any profits from its

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1 business and is not even projected to do so until fourth quarter 2000 at best. (Vysis' Press
2 Releases, NOL., Exhs. 3, 4.) Vysis' financial straits, coupled with its effort to create needless
3 delay, create a grave concern that the stay will affect Gen-Probe's substantive rights in this case.

4 For example, should Gen-Probe succeed in its claim for unfair competition arising out of
5 Vysis' bad-faith enforcement of the '338 patent, Gen-Probe will be entitled to recoup any royalty
6 payments it pays during the pendency of this action. See Cal. Bus. & Prof. Code Section 17203.⁴
7 However, if, at the delayed conclusion of this case, Vysis is financially unable to make restitution,
8 Gen-Probe's remedy will be hollow. Accordingly, should the Court accept Vysis' motion to delay
9 this case, fairness dictates that the Court impose suitable safeguards to ensure that Vysis does not
10 use the resulting delay to collect extra royalty payments on an invalid patent.

11 **D. The benefits of a stay are limited.**

12 The only real benefit from a stay pending completion of the reissue process is that
13 such a stay would permit the claims of the '338 patent to be finally and permanently fixed before
14 the patent is submitted to scrutiny in this Court. A stay could admittedly preclude two rounds of
15 judicial review of the patent. For this reason - and despite the inevitable delay in reaching the
16 merits -- some courts have felt constrained to stay litigation in light of the possibility that patent
17 claims might be modified in reissue proceedings, particularly where the patentee files the reissue
18 application in the early stages of litigation.

19 **E. The Court should impose reasonable conditions if a stay is granted.**

20 Courts that have granted stays in the circumstances similar to those presented here
21 have also routinely imposed conditions in connection with the stay in order to minimize the
22 prejudice sustained by the other party from the resulting delay in final resolution of the issues. *E.g.*
23 *United Merchants and Manufacturers, Inc. v. Henderson*, 495 F. Supp. 444 (N.D. Ga. 1980).
24 Because Gen-Probe will suffer undue prejudice and competitive injury if the Court stays this case,
25 Gen-Probe respectfully requests that the Court carefully craft appropriate conditions for the stay to
26 minimize the resulting prejudice to Gen-Probe. Any stay imposed by this Court should be a

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28 ⁴ All California Authorities are attached as exhibits to the concurrently filed Notice of Lodgment.

complete stay and should impose proper conditions in order to protect the processes of the Court and minimize prejudice to Gen-Probe. Moreover, the conditions should encourage Vysis to expedite its prosecution of the reissue application.

Gen-Probe requests that if the Court grants Vysis' motion, the Court also impose the following conditions:

- Vysis should promptly advise the Patent Office of the pendency of this litigation and petition for special litigation processing of the reissue application, as required by the Manual of Patent Examination Procedure § 1442.04;
- Vysis should agree to forego any continuation practice (or, alternatively, should Vysis desire or attempt to pursue any continuation of the pending reissue proceeding, the Court should promptly vacate the stay) (*Cf. United Sweetener*, 766 F.Supp. at 218-219 (stay would automatically lift at pre-determined point of Patent Office proceedings to prevent the use of appeals solely to delay the case);
- Vysis should report in writing to the Court and Gen-Probe on 60-day intervals concerning the status of the reissue proceedings (*ASCII Corp. v. STD Entertainment, Inc.*, 844 F.Supp. 1378 (N.D. Cal. 1994); *Dennco, Inc. v. Cirone*, 1995 US Dist. Lexis 9988 (D.N.H. 1995).);
- Vysis should notify the Court and Gen-Probe within ten days when the Patent Office issues its final office action on the initial reissue application;
- The parties should establish an escrow account into which Gen-Probe shall pay all royalties due to Vysis under the terms of the license agreement pending the outcome of this action. (This condition serves the dual purpose of providing the most likely motivation for Vysis to expedite the reissue proceedings and the only secure protection to ensure and secure Gen-Probe's entitlement to the return of its royalty payments at the conclusion of this case.⁵)

⁵ As is explained above, an order granting a stay will subject Gen-Probe to unreasonable and unnecessary financial risk. Where, as here, one of the parties is in a state of financial distress, the courts have not been reluctant to condition an order granting a stay on measures to reduce the financial risk to the party opposing the stay. *E.g., Apex Hosiery Co. v. Knitting Machines Corp.*, 90 F. Supp 763, 767 (D. Del. 1950) (stay conditioned on waiver of right to recover damages that

1 IV. THE COURT SHOULD REJECT VYSIS' REQUEST FOR ONE-SIDED DISCOVERY.

2 As part of its motion to stay the case, Vysis asks that the stay be one-sided: Vysis wants to
3 obtain discovery from Gen-Probe to aid it in presenting its position to the Patent Office in the *ex*
4 *parte* reissue proceedings. Among other things, Vysis seeks to obtain discovery of Gen-Probe's
5 NAT kits such that it can further shape any reissue claims to encompass those products.

6 In considering Vysis' motion, it is important to consider that the reissue proceeding in the
7 Patent Office is a one-sided, *ex parte* proceeding, in which Gen-Probe cannot participate in any
8 meaningful way. While Gen-Probe has the right to file a single initial "protest" brief with the
9 Patent Office within the first 60 days following the formal announcement of the reissue
10 proceeding, Gen-Probe is absolutely precluded by regulation from any further participation in the
11 reissue proceedings. 37 C.F.R. § 291(c); *Henkel Corp. v. Coral, Inc.*, 754 F.Supp. 1280, 1298
12 (N.D. Ill. 1990) ("The Patent Office eliminated the opportunity to fully participate as a protester,
13 beyond the submission of an initial written protest, in 1982"); *In re Blaese*, 19 USPQ 2d 1232
14 (Comm'r. Pat. 1991) (the 1982 amendment to Rule 291 was specifically designed to ensure that
15 the proceedings are essentially *ex parte*). Gen-Probe cannot reply to Vysis' response to
16 Gen-Probe's protest, cannot respond in any way to other arguments made by Vysis in writing to
17 the Patent Office, cannot comment on interim Patent Office rulings ("office actions"), cannot
18 respond to Vysis' further amendments of the patent claims (if any), cannot attend the usual
19 informal hearings or "interviews" conducted by the patent examiner to address issues which arise
20 in the proceeding, and cannot participate in any appeal to Board of Patent and Trademark Appeals.
21 *Id.*

22 Vysis' reissue application, and its motion to stay this action, clearly suggest that Vysis
23 intends to try and take advantage of the *ex parte* nature of the reissue proceeding in the Patent
24 Office and, if it is successful there, return to this Court and argue that the court must defer to the
25 Patent Office's decision to issue amended claims. Vysis seeks to keep this case alive solely to

26 would accrue while stay pending); *Bethlehem Steel Corp. v. Tishman Realty & Construction Co.*,
27 *Inc.*, 72 F.R.D. 33 (S.D.N.Y. 1976) (stay conditioned on the posting of a bond); *In re Hayes*
28 *Microcomputer Products, Inc. Patent Litig.*, 982 F.2d 1527 (Fed. Cir. 1992) (percentage of sales
placed in escrow account while injunction stayed during appeal).

permit Vysis to obtain unilateral discovery from Gen-Probe. Vysis seeks to obtain such discovery, which is not available in Patent Office reissue proceedings, in order to bolster its position in the *ex parte* reissue proceeding. At the same time it simultaneously seeks discovery and a stay here, Vysis also seeks to deny Gen-Probe any right to obtain discovery on the issues from Vysis.⁶ If this case is to be stayed, it should be stayed. If discovery is to proceed, then it should proceed for both parties, not just one.

For example, Vysis claims that Gen-Probe's answers to discovery are "necessary for the Court and the parties to gain the full benefit of the reissue proceedings." (*Cf.*, Vysis Memorandum, at p. 8.) Yet, an identical argument may be made for the discovery that Gen-Probe served upon Vysis. That discovery was *also* timely served and, but for the parties' agreement to stay *all* discovery, would already have been answered. Among other things, that discovery seeks Vysis' explanations regarding its claims that Gen-Probe's NAT products infringe the '338 patent, Vysis' proposed construction of the claims of the '338 patent and an identification of all prior art of which Vysis is aware.⁷ Certainly, to the extent that Gen-Probe's responses may be "necessary" for the Court and the parties, Vysis' responses may provide an even better standard by which the Court may ultimately assess the validity and propriety of Vysis' conduct in the reissue proceedings.

It would be manifestly unfair to permit Vysis to obtain one-sided discovery through this case, which would be otherwise stayed, in aid of Vysis' *ex parte* proceeding in the Patent Office.

⁶ Among the various facets of unfairness inherent in Vysis proposed unilateral discovery stay is the fact that the proposal would impose significant discovery costs on Gen-Probe. Yet, Vysis would avoid, or at a minimum defer, its own discovery costs for a significant amount of time. Moreover, to the extent that Vysis' motivation for the unilateral discovery stay is to aid the reissue proceeding, Gen-Probe has submitted corresponding discovery requests to Vysis that will go far to ensure Vysis' prompt and orderly disclosure of all prior art and related disclosures during the reissue. (See Gen-Probe's Discovery, NOL, Exhs. 5, 6.) The information sought by these requests will assist Gen-Probe in preparing its protest papers because it will (1) identify all of the material prior art possessed by Vysis, and (2) ensure that Gen-Probe (and the Patent Office) is aware of the scope of the claims asserted by Vysis. Both of these aspects are important to ensure that the Patent Office will be appraised of all the issues and art raised by Vysis' reissue.

⁷ Gen-Probe has also sought discovery of relevant documents from various third parties affiliated with Vysis in the prosecution of the '338 patent. (Maloney Decl., ¶ 7.) Gen-Probe has agreed to stay the responses to that discovery pending the outcome of the Court's ruling of the motion to stay. (*Id.*, ¶ 9.)

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1 The Court should either stay this case in its entirety or allow the parties to conduct bilateral
2 discovery.

3 **V. THE COURT SHOULD DENY VYSIS' ALTERNATIVE MOTION TO DISMISS THE UNFAIR**
4 **COMPETITION CLAIM FOR RELIEF.**

5 As an alternative to its motion to stay,⁸ Vysis moves this Court to dismiss Gen-Probe's
6 claim of unfair competition on the grounds that, according to Vysis, it has merely executed a
7 license agreement and thus, according to its argument, has done nothing to "enforce" the '338
8 patent. Through that argument, Vysis relies upon specious reasoning and ignores the fundamental
9 nature of the exclusionary rights inherent in the continued possession and assertion of a United
10 States Patent. Vysis also ignores the accepted facts of the invalidity of the '338 patent and Vysis'
11 express and implicit threats to enforce the '338 patent through litigation which induced the license
12 agreement in the first instance. That argument also ignores significant Federal Circuit precedent
13 that has recognized Gen-Probe's unfair competition claim.

14 To begin with, it is impossible to ignore the exceptionally high procedural burden that Rule
15 12(b)(6) imposes upon Vysis' effort to dismiss the fourth count. The Ninth Circuit has repeatedly
16 cautioned that dismissal under Rule 12(b)(6) is proper only in extraordinary circumstances. *See,*
17 *e.g., United States v. City of Redwood City*, 640 F.2d 963, 966 (9th Cir. 1981). District Courts may
18 not dismiss claims under Rule 12(b)(6) "unless it appears beyond doubt that the plaintiff can prove
19 no set of facts in support of [its] claim that would entitle [it] to relief." *Schneider v. California*
20 *Department of Corrections*, 151 F.3d 1194, 1196 (9th Cir. 1998). Furthermore, as noted above,
21 this Court must accept as true the facts that Gen-Probe asserts in its complaint. *E.g., Cooper v.*
22 *Pickett*, 137 F.3d at 623.

23 Accordingly, the Court must consider Vysis' motion in the context of several dispositive
24 facts. First, the claims of the '338 patent are invalid in all material respects and the patent is
25 unenforceable. (First Amended Complaint, ¶¶ 22, 30.) Furthermore, to the extent that a court
26 would, or could, narrowly construe any of the claims of the '338 patent in a fashion to maintain

27
28 ⁸ The inclusion of the alternative motion within the motion to stay papers is contrary to Local Rule
7.1, which requires each motion to be separately stated and separately supported.

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1 any semblance of validity, such construction would *not* encompass any of Gen-Probe's products.
2 (*Id.*, ¶ 22.)

3 In addition, Vysis *knows* that the '338 patent is invalid and unenforceable. *Id.*, at ¶ 35.
4 Despite that knowledge and in bad faith, Vysis has continued to enforce the '338 patent. *Id.*
5 Based upon the facts alleged in the complaint, the Court must deny Vysis' alternative motion to
6 dismiss the fourth count for unfair competition.

7 Gen-Probe's claim for unfair competition presents a cognizable claim arising from Vysis'
8 previous and continuing acts of unfair competition. Thus, the Court must deny Vysis' alternative
9 motion to dismiss Gen-Probe's fourth claim for relief.

10 For example, Gen-Probe alleges that Vysis' conduct violates Section 17200 of the
11 California Business and Profession Code. This statute proscribes any unlawful, unfair or
12 fraudulent business practice or conduct. *Cel-Tech Communications, Inc. v. Los Angeles Cellular*
13 *Telephone Co.*, 20 Cal.4th 163, 180 (1999). This multi-faceted claim encompasses fraudulent
14 practices that are likely to deceive members of the public. *See Saunders v. Superior Court*, 27
15 Cal.App.4th 832, 839 (1994). Thus, unlike common law fraud, a plaintiff may establish a Section
16 17200 violation even if no one was actually deceived, relied upon the fraudulent practice, or
17 sustained any damage. *E.g., Bank of the West v. Superior Court*, 2 Cal. 4th 1254, 1267 (1992).

18 As a further prong of Section 17200, the California courts have construed an "unlawful
19 business practice" as any violation of law whether civil or criminal, federal, state or municipal,
20 statutory, regulatory, or court-made. *E.g., Stevens v. Superior Court*, 75 Cal.App.4th 594, 606
21 (1999). Finally, an unfair business practice, at least between competitors, includes any acts or
22 practices that "threatens an incipient violation of the antitrust law, or violates the policy or spirit of
23 one of those laws because its effects are comparable to or the same as a violation of the law, or
24 otherwise significantly threatens or harms competition." *Cel-Tech*, 20 Cal.4th at 187.

25 The accepted facts and inferences attendant with Gen-Probe's fourth count make clear that
26 Vysis' acts of bad-faith enforcement of an invalid patent constitute unlawful, unfair or fraudulent
27 business practices or conducts in violation of Section 17200.⁹

28 ⁹ Technically, the first inquiry under Section 17200 is whether another law bars the unfair
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1 Accordingly, at this procedural juncture, the statutory presumption of validity arising from
2 35 U.S.C. 282 is a smoke screen raised by Vysis to blur the Court's vision. Rather, the Court must
3 accept the fact of invalidity and unenforceability - coupled with Vysis actual knowledge of those
4 defects. The Court must also assume that Vysis knows that Gen-Probe's NAT products do not
5 infringe any valid claim of the '338 patent. (*Id.*, ¶ 22.)

6 Accordingly, at this procedural juncture, Vysis cannot hide behind the statutory
7 presumption of validity arising from 35 U.S.C. 282¹⁰. Rather, the Court must accept that the fact
8 of invalidity and unenforceability - coupled with Vysis actual knowledge of those defects. The
9 Court must also assume that Vysis knows that Gen-Probe's NAT products do not infringe any
10 valid claim of the '338 patent. (*Id.*, ¶ 22.)

11 Vysis' argument that it has *merely* entered into a license agreement and thus has not
12 "enforced" the invalid patent claims ignores reality and the further allegations of Gen-Probe's
13 complaint. For example, soon after the '338 patent issued, Vysis first implemented its
14 enforcement efforts for the '338 patent by contending that the '338 patent applied to Gen-Probe's
15 NAT products. (*Id.*, ¶ 20). Particularly given the litigious nature of Vysis and its predecessor-in-
16 interest, Amoco Technology Corporation, (*see id.*, ¶ 25), that "suggestion" provided a clear
17 warning to Gen-Probe that Vysis would sue for infringement should Gen-Probe fail to acquiesce
18 to Vysis' demand for royalty payments under a license agreement. (*See Id.*, ¶¶ 20, 25.) That
19 evidence fully satisfies the requisite showing of unlawful and fraudulent conduct. In addition,
20 given the statutory monopoly that accompanies the grant of a United States Patent, coupled with

21
22 competition action. *Cel-Tech*, 20 Cal.4th at 184. Vysis has not challenged this issue - and for good
23 reason. No state law bars this claim and, in a series of decisions, the Federal Circuit has
24 established that federal patent law does *not* preempt state law claims for unfair competition that
25 depend upon facts of bad-faith enforcement of invalid patents. *E.g.*, *Zenith Electronics Corp. v.*
26 *Exzec Inc.*, 182 F.3d 1340, 1355 (Fed. Cir. 1999).

27 ¹⁰ The presumption of patent validity is purely a *procedural* device. It simply assigns to the party
28 that asserts that a patent is invalid the burden of proving invalidity. *Avia Group International, Inc.*
v. L.A. Gear California, 853 F.2d 1557, 1562 (Fed. Cir. 1988); *In re Etter*, 756 F.2d 852, 856
(Fed. Cir. 1985). The presumption does not have any substantive evidentiary significance. *New*
England Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 882 (Fed. Cir. 1992) (presumption
insufficient to establish probability of success on the merits in context of injunctive relief);
Nutrition 21 v. United States, 930 F.2d 862, 869 (Fed. Cir. 1991) (same).

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1 Vysis' knowledge that the claims of the '338 patent were invalid and did *not* apply to Gen-Probe's
2 products, that prior conduct of Vysis establishes the alternative prong of unfairness. *See, e.g.,*
3 *Argus Chemical Corp. v. Fibre Glass-Evercoat Co.* 812 F.2d 1381, 1386 (Fed. Cir. 1987).

4 Furthermore, even disregarding the early evidence of Vysis' unlawful, unfair or fraudulent
5 business practices and conduct, Gen-Probe has also alleged Vysis' *continuing activities* by which it
6 has continued to enforce the '338 patent notwithstanding actual knowledge of the invalidity,
7 unenforceability and non-infringement of the '338 patent. Specifically, to eliminate any doubt
8 concerning Vysis' knowledge that the claims of the '338 patent are invalid and that Gen-Probe's
9 products do not infringe, Gen-Probe alleged the facts substantiating its recent disclosure to Vysis
10 of prior art references that invalidate the claims of the '338 patent. (First Amended Complaint,
11 ¶ 23.) In the face of that further disclosure and notwithstanding Vysis' actual knowledge of the
12 invalidity and unenforceability of the '338 patent, Vysis has persisted in its public denial and has
13 continued to insist that the '338 patent is valid and that Gen-Probe's NAT products infringe that
14 patent. (*Id.*, ¶ 24.) This conduct alone satisfies the fraudulent prong of Section 17200.¹¹

15 Moreover, the argument that Gen-Probe's remedy for Vysis' fraudulent enforcement of a
16 knowingly invalid patent is merely to cease royalty payments ignores the fact, as alleged, that Gen
17 Probe's failure to render royalty payments will result in Vysis' aggressive efforts to terminate the
18 license agreement and initiate infringement suits against Gen-Probe and its allied collaborators and
19 customers. (First Amended Complaint, ¶ 25.) That continuing threat of aggressive litigation
20 provides still further evidence of the enforcement muscle that Vysis wields through the '338 patent
21 and the license agreement.

22 ///

23 ¹¹ As indicated above, Gen-Probe has shown an adequate basis for its unfair competition claim and
24 further shown that the claim does not depend upon Vysis' supposition of a claim for "wrongful" or
25 malicious defense. (Vysis' Memorandum, at p. 10-11.) Nonetheless, Gen-Probe notes that Vysis'
26 proposition that it cannot be guilty of unlawful, unfair or fraudulent business practices, as a matter
27 of law, for "merely" enforcing a patent license agreement prior to *compelling* a judicial
28 determination of invalidity presents a troubling argument. Gen-Probe suggests that an independent
claim for unfair competition and anti-competitive activity will arise should Gen-Probe ultimately
prevail and prove that, notwithstanding Vysis' *actual knowledge* of invalidity, it nonetheless
judicially denied such knowledge and *forced* a judicial finding of invalidity in order to continue to
collect royalties on an invalid patent pursuant to its license agreement.

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1 Finally, Vysis' fraudulent conduct in violation of Section 17200 is virtually established
2 through the pleadings coupled with Vysis' response to Gen-Probe's disclosure of invalidating prior
3 art. (*See Id.*, ¶¶ 23-24.) As the extrinsic evidence proffered by Vysis discloses, Vysis initially
4 responded to Gen-Probe's proffer by denying *any* infirmity in the '338 patent. (*See* Galloway
5 letter dated January 19, 2000, Vysis Exh. C.) Yet, notwithstanding this response, Vysis then
6 initiated reissue proceedings in an attempt to "cure" the invalidating defects that Gen-Probe
7 brought to Vysis' attention. Vysis' reissue declaration at least tacitly evidences its concern that the
8 broad claims of the '338 patent are invalid in light of the prior art that Gen-Probe submitted. That
9 tacit concern raises a strong inference of a violation of section 17200 when viewed in the context
10 of Vysis' January 13, 2000 response to Gen-Probe.

11 Thus, the Court must deny Vysis' alternative motion to dismiss Gen-Probe's fourth count
12 for Unfair Competition. Given the facts of Vysis' knowledge of the invalidity, non-infringement
13 and unenforceability of the '338 patent, Vysis cannot show beyond doubt that Gen-Probe can
14 prove no set of facts in support of its claim that would entitle it to relief. *See, e.g., Schneider v.*
15 *California Department of Corrections*, 151 F.3d 1194, 1196 (9th Cir. 1998).

16 As a corollary to the *present* viability of Gen-Probe's claim for unfair competition, that
17 claim will remain viable notwithstanding the outcome of Vysis' resort to reissue proceedings.
18 Thus, to the extent that Vysis purports to buttress its motion for a stay upon express or implied
19 suggestions that the reissue proceeding can dispose of the entire case, that argument is simply
20 wrong and misrepresents the limited nature of reissue proceedings.

21 First, there are a discrete number of outcomes of the reissue proceeding. None of those
22 outcomes will obviate this litigation and, in particular, Gen-Probe's claim for unfair competition.
23 For example, irrespective of the Patent Office's decision on reissue, this Court retains jurisdiction
24 to review any reissue patent, to determine the validity of the reissue claims, and to evaluate Vysis'
25 past and future conduct before the Patent Office and in enforcing the invalid '338 patent. Because
26 this Court is *not* bound by any determination of the Patent Office, (*e.g., Yates-American Machine*
27 *Co., Inc. v. Newman Machine Co., Inc.*, 694 F. Supp. 155, 158 (M.D.N.C. 1988).), Gen-Probe's
28 unfair competition claim will remain viable even under the best of reissue outcomes for Vysis.

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1 Second, reissue proceedings cannot adjudicate or resolve acts of inequitable conduct
2 committed in the prosecution of the original patent. E.g. MPEP 1448 ("The Office no longer
3 investigates and rejects reissue applications under 37 CFR 1.56. The Office will not comment
4 upon any duty of disclosure issues which are brought to the attention of the Office in reissue
5 applications"); see also, *Enprotech Corp.*, 15 U.S.P.Q. 2d 1319. Based upon the limited
6 evidence available to date, and particularly when viewed in the context of the tortured prosecution
7 of the '338 patent, Gen-Probe believes that the issue of inequitable conduct and resulting
8 unenforceability will remain for resolution. Even assuming, *arguendo*, that the Patent Office and
9 this Court determine that *all* of the original and reissue claims, if any, are valid, Gen-Probe's
10 unfair competition claim will remain viable to the extent that Vysis has enforced -- and continues
11 to enforce -- a patent that is unenforceable due to the inequitable conduct committed by it or its
12 predecessor in interest.

13 VI. CONCLUSION.

14 As set forth above, a stay will not ultimately eliminate or dispose of Gen-Probe's claims.
15 Nonetheless, should the Court impose a stay, the Court should impose suitable conditions to
16 minimize the prejudice that Gen-Probe will sustain from the delay that will result from Vysis'
17 reissue proceedings.

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1 If a stay is granted but Vysis fails to prosecute the reissue application with utmost
2 diligence, Gen-Probe reserves the right to move to vacate the stay. *United Merchants & Mfrs., Inc.*
3 *v. Henderson*, 495 F. Supp. 444, 447 (N.D. Ga. 1980); *Reiter v. Universal Marion Corporation*,
4 173 F. Supp. 13, 17 (D. D.C. 1959).

5 Dated: April 10, 2000

6 COOLEY GODWARD LLP
7 STEPHEN P. SWINTON (106398)
8 JAMES J. DONATO (146140)
9 PATRICK M. MALONEY (197844)

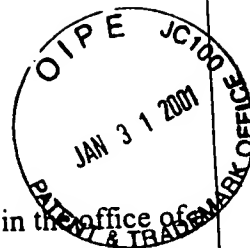
10 GEN-PROBE INCORPORATED
11 R. WILLIAM BOWEN, JR. (102178)

12 By: Patrick M. Maloney
13 Patrick M. Maloney

14 Attorneys for Plaintiff,
15 GEN-PROBE INCORPORATED

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PROOF OF SERVICE (FEDERAL EXPRESS)



I, Lindsay Dillow, hereby declare:

I am employed in the City of San Diego, County of San Diego, California in the office of [redacted] member of the bar of the court in which the within action is pending at whose direction the following service was made. I am over the age of eighteen years and not a party to the within action. My business address is Cooley Godward LLP, 4365 Executive Drive, Suite 1100, San Diego, California 92121-2128. I am personally and readily familiar with the business practice of Cooley Godward LLP for collection and processing of notices and other papers to be sent by overnight delivery service by Federal Express. Pursuant to that business practice, envelopes and packages are placed for collection at designated stations and in the ordinary course of business are that same day deposited in a box or other facility regularly maintained by such express service carrier or delivered to an authorized courier or driver authorized by such express service carrier to receive documents, in an envelope or package designated by such express service carrier, with delivery fees paid or provided for.

On April 10, 2000, I served: NOTICE OF LODGMENT IN SUPPORT OF GEN-PROBE INCORPORATED'S RESPONSE TO VYSIS' MOTION: (1) FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, (2) TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B) (6), DECLARATION OF PATRICK M. MALONEY IN SUPPORT OF GEN-PROBE INCORPORATED'S RESPONSE TO VYSIS' MOTION: (1) FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, (2) TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B) (6) AND MEMORANDUM OF POINTS AND AUTHORITIES OF GEN-PROBE INCORPORATED IN RESPONSE TO VYSIS' MOTION: (1) FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, (2) TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6) on the interested parties in this action by placing a true copy thereof, on the above date, enclosed in a sealed envelope, at a station designated for collection and processing of envelopes and packages for overnight delivery service by Federal Express as part of the ordinary business practice of Cooley Godward LLP described above, addressed as follows:

PROOF OF PERSONAL SERVICE

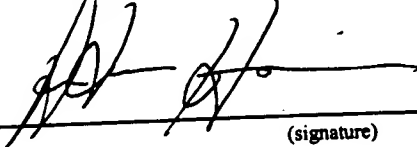
I, ANDREW HARRISON, hereby declare:

I am employed in the City of San Diego, County of San Diego, California; I am over the age of eighteen years and not a party to the within action; my business address is Advanced Attorney Service, 1785 Hancock Street, Suite 200, San Diego, CA 92110.

On April 10, 2000, I served the within: NOTICE OF LODGMENT IN SUPPORT OF GEN-PROBE INCORPORATED'S RESPONSE TO VYSIS' MOTION: (1) FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, (2) TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B) (6), DECLARATION OF PATRICK M. MALONEY IN SUPPORT OF GEN-PROBE INCORPORATED'S RESPONSE TO VYSIS' MOTION: (1) FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, (2) TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B) (6) AND MEMORANDUM OF POINTS AND AUTHORITIES OF GEN-PROBE INCORPORATED IN RESPONSE TO VYSIS' MOTION: (1) FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, (2) TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6) on the interested parties in this action by personally hand delivering a copy of said document(s) to the address(es) listed below:

John H. L'Estrange, Jr. Esq.
Wright and L'Estrange
701 B Street, Suite 1550
San Diego, CA 92101
Tel: (619) 231-4844
Fax: (619) 231-6710
Attorneys for Vysis, Inc.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on April 10, 2000.

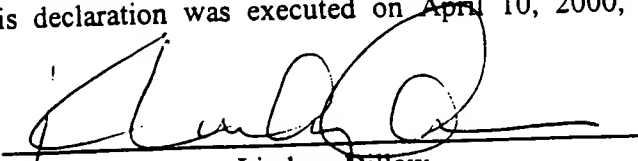

(signature)

ANDREW HARRISON
(print name)

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3 1300 I Street, N.W., Suite 700
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Palo Alto, CA 94304
Tel: (650) 849-6600
Fax: (650) 849-6666
Attorneys for Vysis, Inc.

8 I declare under penalty of perjury under the laws of the State of California that the
9 foregoing is true and correct, and that this declaration was executed on April 10, 2000, at
10 San Diego, California.

11 
12 _____
13 Lindsay Dillow
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